Remarks

This Amendment is filed in reply to the Office Action mailed August 31, 2004. Reconsideration of the present application in view of the foregoing amendments and following remarks is respectfully requested.

Claims 2-4, 6-9 and 14-18 were addressed in the Office Action. Claim 2 is amended. Claims 6 and 7 are cancelled. New claims 19 – 29 are added. Accordingly, claims 2-4, 8-9 and 14-29 are not pending.

In the Office Action, claims 6 and 7 were objected to, claims 2-4 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, claims 14-17 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,682,472 to Davis, claims 2-4, 6-9 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Davis (claim 18), over U.S. Patent No. 6,377,693 to Lippa et al. (claims 2-4), or over Lippa in view of Davis (claims 6-9). These rejections are respectfully traversed based upon the foregoing amendments and the following remarks.

New claims 19 – 29 are supported in the specification in paragraphs [0020] through [0055] of the published application (US 2001/0051776 A1 published December 13, 2001), and thus do not introduce new matter. New claims 19-29 were previously pending in U.S. Application No. 10/135,395 from which the present application claims priority as a continuation-in-part.

Objections to Claims 6 and 7

As discussed more fully below, claims 6 and 7 are cancelled without disclaimer or prejudice in order to further the prosecution of the remaining claims.

Rejection under 35 U.S.C. § 112, second paragraph

In the Office Action, claims 2-4 were rejected under Section 112, second paragraph, because the phrase "the ultrasound unit" recited in claim 2 lacks antecedent basis. Claim 2 has been amended to replace "the ultrasound unit" with "the upper audio frequency source" which has antecedent basis. Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 2-4 under Section 112, second paragraph. Applicant considers this amendment to be consistent with the intended meaning of the original claim in that "the ultrasound unit" should have been "the upper audio frequency source". Thus, this amendment does not narrow the scope of the claim.

Rejections under 35 U.S.C. § 102(e)

The Office Action rejects claims 14-17 as being anticipated by Davis based upon the interpretation that the predetermined masking algorithm taught in Davis satisfies the at least one tone within the range of 10Hz to 20Hz recited in claim 14. This rejection is respectfully traversed for the following reasons.

Davis discloses a method for providing relief to a person suffering tinnitus that spectrally modifies an audio signal in accordance with a "masking algorithm" that modifies the intensity of the audio signal at selected frequencies. *See* Davis Abstract, Fig. 6E, 2:30-4:21, 6:65-7:32. Davis teaches that the "masking algorithm" is a volume equalization template "derived by subtracting the base line from the hearing threshold ... for each frequency and each ear." 7:10-12 (emphasis added). The disclosed masking algorithms are defined at 7:15-32 and 10:32-12:10. Tables 3 and 4 show example algorithms for two patient hearing loss profiles, which show that the volume of selected frequency bands is adjusted based upon the hearing loss profile. The volume adjustments are expressed in dB SPL (sound pressure level). *See* 11:2-5. Thus, Davis teaches adjusting the volume of a single noise source, such as music, at selected frequency bands based upon the measured hearing loss of a patient. The result will be a sound, such as music, that is equalized across selected frequencies and both ears to compensate for the patient's unique hearing loss pattern. *See, e.g.,* Fig. 2 and

description at 7:35-50. Davis does not disclose a second sound source used in the masking algorithm.

In contrast, claim 14 recites a very different method of treating tinnitus. Specifically, a music source (a first sound source) is multiplied by a second tone (which may be a single tone, white noise or tones swept across a spectrum) in the upper audio range (10 kHz to 20 kHz), which will produce a pulsating tone in the upper audio range. The resulting tone is not recognizable as music but will have the pleasant temporal or timbre of music. *See* published application at ¶ 0060.

Davis does not teach nor suggest multiplying a music source by a tone as recited in claim 14. The "masking algorithm" used to equalize a sound source to compensate for a patient's specific hearing loss that is disclosed in Davis is not the same as nor in any way equivalent to multiplying by a tone. Further, the resulting therapy provided to a patient by Davis, which is an equalized sound or music output that remains consistent with the input source, is entirely different from the pulsating tone in the upper audio range generated by the invention recited in claim 14. Thus, this element of claim 14 is not disclosed or even suggested in Davis.

Since Davis fails to teach at least one element of claim 14, Applicant submits that the claim is allowable over Davis. Further, since claims 15-17 depend from allowable claim 14, Applicant further submits that these claims are also allowable over Davis. Accordingly, withdrawal of the rejections of claims 14-17 are respectfully requested.

Rejections under 35 U.S.C. § 103(a)

The individual rejections under Section 103(a) are address below.

Rejection of Claim 18

The Office Action rejects claim 18 as unpatentable over Davis on the basis that it would have been obvious to provide noise as the masking algorithm. This rejection is respectfully traversed for the following reasons.

As the foregoing discussion points out, Davis discloses a volume adjusting algorithm that equalizes a sound source, such as music, across audible frequencies to compensate for a particular patient's hearing loss at various frequencies and for both ears. Davis teaches individually defining such "masking algorithms" to specifically compensate for each patient's hearing profile. Thus, Davis teaches away from randomly modifying a music source as would be the case if noise were substituted for the masking algorithm. Therefore, Davis teaches away from the modification suggested by the Examiner. Thus, Applicant submits that claim 18 is allowable over Davis.

Applicant also submits that claim 18 is allowable for the additional reason that claim 18 depends from claim 14 which is allowable over Davis as addressed above.

Accordingly, Applicant respectfully requests withdrawal of the rejection of claim 18.

Rejection of Claims 2-4

In the Office Action, claims 2-4 are rejected as being unpatentable over Lippa on the basis that it would have been obvious to adjust the volume in Lippa to no more than 20dB greater than a threshold level of a person (claim 2) and to sweep over a range of frequencies within the range disclosed in Lippa. While Applicant disagrees that it would have been obvious to modify Lippa as suggested, these rejections are respectfully traversed because even if Lippa is so modified, the result does not disclose every element of claims 2-4.

Specifically, Lippa discloses transposing an inputted noise signal "into the ultrasonic frequency range, which is above 20,000 hertz and extends to approximately the 100,000 hertz range." 2:11-14 (emphasis added). This ultrasound signal is applied to a patient by a transducer, electrode or headphones. In contrast, claim 2 of the present invention recites a system that outputs an upper auditory range signal that is applied to a patient via air conduction. As the specification explains, the "upper auditory range" is between 10 kHz to 20 kHz. *See* published application ¶ 0060. Further, claim 3, which depends from claim 2, recites that the upper audio frequency is a frequency of between 10 kHz and 19.9 kHz. Thus, Lippa fails to disclose a structure

that applies an upper auditory range signal to a patient via air conduction as recited in claim 2.

Since Lippa fails to disclose an element of claim 2 even when modified as proposed by the Examiner in the Office Action, Applicant submits that claim 2 is allowable over Lippa. Accordingly, Applicant respectfully requests withdrawal of the rejections of claim 2 and of claims 3 and 4 which depend from claim 2.

Rejection of Claims 6-9

In the Office Action, claims 6-9 are rejected as unpatentable over Lippa in view of Davis. While Applicant maintains that claims 6 and 7 are allowable over the cited references, these claims are cancelled without disclaimer or prejudice in order to further the prosecution of the present application. The rejections of claims 8 and 9 are respectfully traversed for the following reasons.

As described more fully above, Lippa teaches transposing auditory noise signals into the ultrasonic frequency range above 20,000 hertz and Davis teaches equalizing a sound, such as music, via a mask algorithm that compensates for a patient's specific hearing loss.

In contrast, claim 8 recites mixing an input sound signal with an upper audio frequency signal to obtain a mixed signal. Neither of the asserted references disclose the generation of a mixed signal, nor mixing an input signal with an upper audio frequency signal. Further, there is no teaching in either reference that would suggest either of these elements of claim 8.

Applicant respectfully disagrees that there is motivation to combine the two references as proposed, since the Lippa reference teaches transposing the input sound into the ultrasonic region where the music source disclosed in Davis could only be perceived by bone conduction *(see* Lippa at 2:47-51), thereby rendering the mask algorithm teachings of Davis inoperable. Further, Lippa teaches providing an ultrasonic stimuli above 20 kHz that will not interfere with the perception of speech or other normal sounds, which is counter to teaching of Davis to provide a sound (e.g., music) source

that is equalized across frequencies and ears to compensate for a patient's hearing loss. Thus, the combination suggested would render a primary objective or feature of one reference inoperable. Further, since Lippa teaches the generation of an inaudible signal while Davis teaches adjusting the volume of various frequencies of an audible signal to compensate for hearing loss, these references actually teach away from a combination of their teachings as proposed in the Office Action.

Even if the Lippa and Davis references are combined as proposed by the Examiner in the Office Action, the combination would not disclose all elements recited in claim 8. Specifically, the combination of Davis and Lippa would be an apparatus that applies a masking algorithm to equalize an input source so as to compensate for a patient's hearing loss and then transposes that compensated signal into the ultrasonic frequency range. Since the primary teaching of Davis is the masking algorithm that equalizes a sound across frequencies to compensate for hearing losses, applying the algorithm to an ultrasonic, i.e., inaudible, sound source makes no sense. Nevertheless, this combination fails to disclose mixing an input sound signal with an upper audio frequency signal to obtain a mixed signal as recited in claim 8. Further, the combination would generate an ultrasonic signal to be applied to a patient, and not an audible signal as in claim 8.

In sum, Applicant submits that neither Lippa nor Davis teach or suggest at least one element of claim 8, that there is no motivation or suggestion to combine these references, and that even if the references are combined, the resulting combination fails to disclose all elements of claim 8. Accordingly, Applicant submits that claim 8 is allowable over the cited references and respectfully requests withdrawal of the rejections of claim 8 and of claim 9 which depends from claim 8.

New Claims

Claims 19 – 22 and 26 – 29.

As described in column 2 and in the claims, Lippa teaches a method of treating tinnitus using an ultrasound noise signal. In column 2, Lippa teaches that the

ultrasound noise signal is generated by transposing a noise signal in the auditory range into the ultrasonic frequency range, which is above 20,000 hertz. The resulting ultrasonic noise signal is inputted to an applicator for application to the body. In sum, Lippa merely teaches transposing an audible noise into an ultrasonic frequency noise signal, which is further evident in the statement that "the signals from the noise signal generator may originate in the ultrasonic frequency range in which case an ultrasonic modulator would not be needed." Thus, the "modulator" mentioned in Lippa is used only to generate an ultrasound noise signal from an audible noise input.

In contrast, claims 19 – 22 and 26 – 29 recite a different method of treatment using a different form of vibration input not suggested in Lippa. For example, claim 19 recites providing ultrasound noise that is then modulated in amplitude with a low audio frequency to provide an audio frequency amplitude modulated ultrasound noise with a low frequency periodicity. As recited in claim 29, the low audio frequency may be as low as 1 Hz.

Lippa teaches away from the method recited in claim 19, because Lippa teaches transposing an audible noise signal into the ultrasonic range, i.e., transforming the signal by up-modulating, the exact opposite of down-modulating an ultrasonic noise with a low audible frequency as recited in claim 19. The vibration signal resulting from the Lippa method will have a wave form, characterized by a center frequency in the ultrasound range, that is different from the wave form resulting from the claim 19 method, which will have a center frequency in the low audible range. The perceived signal, and, presumably, the resulting therapeutic effect, will be different. Further, Lippa provides no teaching or suggestion to reverse the up-frequency transformation that Lippa teaches by subsequently modulating the resulting ultrasonic noise signal with a low frequency signal as recited in claim 19.

Claim 23

As discussed above, Lippa teaches applying an ultrasound noise generated by transposing an audible noise into the ultrasound frequency range. Lippa fails to

disclose how the frequency of the ultrasound noise signal should be set and, as discussed above, teaches away from modulating that signal with a low audio frequency.

In contrast, claim 23 recites a method of examining a patient in order to determine an audio frequency amplitude ultrasound treatment for tinnitus that comprises (1) determining an optimum ultrasound frequency for treating the patient, and (2) varying the low audio frequency used to modulate the ultrasound frequency to determine an optimum audio modulating frequency. Thus, claim 23 recites optimizing the treatment on two frequencies, two steps that are not taught or suggested in Lippa.

Claim 24

Claim 24 recites a tinnitus masker in means-plus-function format, including a means for modulating an ultrasonic noise with a low audible frequency. Similar to claim 19, the Lippa reference does not teach a structure that performs the same function.

Claim 25

Claim 25 is similar to claim 19 in reciting providing ultrasound noise or tone by way of an ultrasound unit, wherein said noise or tone is amplitude modulated at an audio frequency. Since this claim element is different in the steps and results from that disclosed in Lippa, Applicant submits that claim 25 is allowable over Lippa.

CONCLUSION

In view of the above amendment and remarks, Applicant respectfully requests that all objections and rejections be withdrawn and that a notice of allowance be forthcoming. The Examiner is invited to contact the undersigned attorney for Applicant at 202-912-2777 for any reason related to the advancement of this case.

Respectfully submitted,

Date: January 31, 2005

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